DEPARTMENT OF HEALTH & HUMAN SERVICES 9/20/01

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mark Reuben, Chairman and CEO
Colgate-Palmolive Company
300 Park Avenue, Fl 8
New York, New York 10002

April 25, 2001

Ref: NYK-2001-62

Dear Mr. Reuben:

This is in reference to "Colgate® Sensitive Maximum Strength Anticavity Toothpaste for Sensitive Teeth" marketed by your firm. The label bears a declaration that the product contains 0.4% stannous fluoride and 5% potassium nitrate as the active ingredients. However, the product is marketed in a dual compartment tube, with one compartment containing approximately 0.9% stannous fluoride in a gel and the other compartment containing 10% potassium nitrate in a paste. The labeling of the tube and carton bears claims that the product is an "anticavity toothpaste for sensitive teeth."

Toothpastes intended to prevent caries and to reduce painful sensitivity of the teeth are considered drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). The final regulations on over-the-counter (OTC) anticaries drug products found at Title 21, Code of Federal Regulations (21 CFR), Part 355 provide the acceptable conditions for marketing an OTC anticaries toothpaste. Additionally, the agency published a notice in the May 11, 1992, Federal Register (57 FR 20114/5) announcing an enforcement policy allowing OTC marketing of oral health care combination drug products containing 5% potassium nitrate as a tooth desensitizing ingredient and any single Category I anticaries ingredient. This enforcement policy also states that marketing of products with labeling that is not in accord with the amended tentative final monograph for OTC oral health care drug products and the (now) final monograph for anticaries drug products may result in regulatory action.

In the "Colgate® Sensitive Maximum Strength Anticavity Toothpaste for Sensitive Teeth," the level of stannous fluoride (0.9%) gel in one compartment of the tube does not conform to the acceptable level under the final monograph (21 CFR 355.20(c)). Further, the level of potassium nitrate (10%) in the other compartment does not conform to the level of the ingredient that is acceptable under the May 11, 1992 enforcement policy on these combination products. There is no assurance that acceptable levels of the active ingredients in "Colgate® Sensitive Maximum

Strength Anticavity Toothpaste for Sensitive Teeth" would be delivered to the surface of the tooth during brushing. We are not aware of any data to show that the combination of stannous fluoride and potassium nitrate, at the levels cited above, is generally recognized by experts as safe and effective for the labeled uses.

The labeling for "Colgate® Sensitive Maximum Strength Anticavity Toothpaste for Sensitive Teeth" states that "There has never been a toothpaste quite like new Colgate®...unique, patented formula delivers maximum strength relief to soothe sensitive nerves inside your teeth...has an advanced dual-formula tube containing both a white paste and a blue gel. The unique formula provides maximum strength to sensitive teeth." These statements imply that the dual formula, i.e., stannous fluoride and potassium nitrate, provide relief to sensitive teeth. There are no provisions in the "permission to market policy" for this combination of ingredients cited above that allow claims to be made for a desensitizing effect by the stannous fluoride component of the formula. Any representation in the labeling that stannous fluoride is instrumental in providing relief to sensitive teeth causes the product to be a "new drug."

Based on the information cited above, we consider "Colgate® Sensitive Maximum Strength Anticavity Toothpaste for Sensitive Teeth" to be a new drug as defined by section 201(p) of the Act, and its marketing violates section 505(a) of the Act because there is no approved new drug application (NDA) for this product. The product is also misbranded (section 502(f)(1) of the Act) because it fails to bear adequate directions for use in the conditions for which it is offered.

The above is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure that all drug products you manufacture and distribute are in compliance with the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in further regulatory action, including seizure and/or injunction without further notice.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps that you have taken to correct these violations. If corrective actions cannot be completed within 15 working days, state the reasons for the delay and the time frame within which the corrections will be made.

Additionally, the May 11, 1992 enforcement policy permitting the marketing of the combination of potassium nitrate with an anticaries agent also addressed the appropriate "statement of identity" that is to be used on such a product. The "statement of identity" for the permitted combination is listed as "...(insert dosage form, e.g., "toothpaste" or "dental gel") for (select one of the following: "sensitive" or "hypersensitive") "teeth and cavity prevention." (57 FR 20115).

Your reply should be sent to Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions, Ms. Aveta's telephone number is 718-662-5576.

Sincerely,

Edward W. Thomas
Acting District Director
New York District